UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,457	01/05/2001	Anders Larsson	PL-9813	8539

26271 7590 09/24/2004

FULBRIGHT & JAWORSKI, LLP
1301 MCKINNEY
SUITE 5100
HOUSTON, TX 77010-3095

EXAMINER	
HANDY, DWAYNE K	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,457	LARSSON ET AL.	
	Examiner	Art Unit	
	Dwayne K Handy	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,22-28,31,33,36 and 41-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,22-28,31,33,36 and 41-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/9/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 20-26, 31, 33, 36 and 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (6,143,248) in view of Burns et al. (6,379,929). The Examiner believes applicant to be familiar with this rejection since it was applied in the previous Office Action. It has been reproduced below for applicant's convenience. **This rejection is still in effect. Please see Response to Arguments below.**

As stated in the previous action (paragraph 3), Kellogg teaches a microfluidic device comprised of a circular disc which contains a microfluidic network. Fluid flow is controlled in the network through the use of capillary valves based on surface tension differences. Specifically, the surface tension differences are created through the use of hydrophobic/hydrophilic junctions between sections of the microfluidic

network. The following passage shows how Kellogg uses these surface properties for valving purposes between a reservoir and a microchannel:

(110) 2. Centrifugal rotors, microplatforms and Microsystems arc also fabricated comprising material having contact angles <90.degree and other material having contact angles >90.degree. For example, using aqueous solutions a fluid reservoir may be hydrophilic (contact angle <90.degree.), whereas a tube or channel is fabricated from a material having a contact angle >90.degree. (thereby requiring positive pressure to be applied to motivate fluid flow from the reservoir into the channel).

Kellogg does not teach a hydrophobic section within a hydrophilic pathway as is now recited in the instant claims. Instead, Kellogg teaches an entire channel comprised of a hydrophobic material which borders a hydrophilic chamber or reservoir. This teaching was also cited by applicant in their response to the previous Office Action (page 7).

Burns et al. (6,379,929) teaches a chip based microfluidic device which also controls fluid flow in the channels through the use of areas of differing surface tensions. Burns discusses this in columns 7 and 8. Burns also shows an example in Figures 3A and 3B (described in columns 35 and 36). This embodiment of the device is described in column 35 and includes a hydrophobic region (40) which is used to stop fluid in the middle of a channel for flow control (column 8, lines 1-10). It would have been obvious to combine the hydrophobic patches from Burns with the device of Kellogg. The use of hydrophobic regions within the channel would allow for multiple valves within a channel which could be used to stop fluid flow in several places instead of at just one interface. It would also lower the energy requirement for moving liquids further down the channels of the microfluidic network since Kellogg teaches a channel which is *entirely* hydrophobic and must use centripetal force for driving fluids through the entire channel.

As for the limitation of a channel outlet as recited in claim 25, it would have been obvious to one of ordinary skill in the art to provide an outlet for the channels in the microfluidic network. One would provide a channel outlet toward the end of the channel to remove materials from the channel so that either the channel may be filled again, or to further process the contents of the channel.

3. Claims 27-28 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (6,143,248) and Burns (6,379,929) and further in view of Sheppard, Jr. et al. (6,143,247). Kellogg and Burns, as described above in paragraph 2, teach every element of claims 27-28 and 41 except for treating the channels to enable cell culture and treating the substrate with plasma treatment. Sheppard also teaches a circular device for detecting and quantifying particulate matter suspended in a fluid. The invention provides an integrated, affinity-binding based, analytical system comprising a platform for performing an affinity-binding based assay for specifically binding particulates including microbial cells, and a detection means for detecting the particulates specifically bound to a defined surface or chamber comprising the platform. Methods for using the analytical systems of the invention are also provided. Sheppard specifically mentions cell capturing and testing in column 4, lines 31-60. Sheppard also teaches surface modification through plasma deposition (column 16, lines 9-37) - including the use of materials that will attract and bind cellular material. It would have been obvious to one of ordinary skill in the art to combine the plasma coating of the cell affinity material of Sheppard with the device and methods of Kellogg. One would add the cellular material to perform capture and analysis of cellular material as taught by Sheppard. One would use the plasma coating method since it is a well-known substrate coating method which can be used to coat the cellular affinity materials of Sheppard onto a substrate.

Response to Arguments

4. Applicant's arguments filed 08/09/2004 have been fully considered but they are not persuasive. Applicant has argued that the combination of the references is improper since Burns does not address "valving". The Examiner respectfully disagrees and directs applicant to columns 33, line 57 – column 34, line 41 of Burns. In this section of Burns' disclosure, under "Fluid Movement", several different embodiments for moving microdroplets through a channel are disclosed. In each case, however, a hydrophobic patch or region was used in conjunction with a driving force (general pressure source, gas source, gas vent) to stop and then restart movement of a fluid through a channel. This is analogous to the way in which Kellogg controls fluid movement in their device. Kellogg uses a change in cross sectional area as well as a change in surface property to stop fluid from fluid out of a reservoir and into a channel. Kellogg uses centripetal acceleration as the driving force however. The Examiner believes this combination of features (non-mechanical stopping feature + addition of a driving force) describe what one of ordinary skill in the art would call a passive valve. This combination of features is also discussed in column 15, lines 13-45 under the term "capillary valve".

5. The Examiner agrees that Burns repeatedly points out that their system does not require the use of valves. The Examiner believes this to be a reference to ***active*** valving systems however and not a teaching away from "valves". Burns still uses

various embodiments of passive valves as described above to form the droplets and move them through channels in the device.

6. Applicant has also argued that one of ordinary skill in the art would concentrate on the use of active (sealed) valves in Burns and that hindsight would be required for one of ordinary skill in the art to choose only the hydrophobic patch teaching. The Examiner respectfully disagrees. The Examiner believes that Burns provides an improvement on the use of passive valve systems as taught by Kellogg. As stated above, both references address the problem of moving fluids through the device using analogous valving systems. Both Burns and Kellogg teach the use of a change in surface property (hydrophilic/hydrophobic), but Kellogg also uses a change in channel cross sectional area to stop fluid flow. The Examiner believes one of ordinary skill in the art would recognize that the stopping mechanism of Burns – the hydrophobic patch – would require less on an energy input to move the fluid move again that the stopping mechanism of Kellogg – which has an entire hydrophobic channel and a change in cross sectional area. Therefore, Kellogg could still use the centripetal force to drive fluids through the channels of their device – only now less force would be required. This is what the Examiner was referring to in the previous action when it was suggested that using Burns' hydrophobic patch would save energy.

7. In summary, Kellogg teaches a circular disc adapted for rotation and having two substrates with a hydrophilic pathway. Kellogg does not teach a hydrophobic patch.

Instead, Kellogg uses a passive valve that is comprised of two features – a change in surfaces and an increase in the cross sectional area. Burns teaches a passive valve comprised of one feature – the change in surface provided by a hydrophobic patch. The Examiner believes that one of ordinary skill in the art would recognize that the stopping feature of Burns would be an improvement on the stopping feature of Kellogg since it does not require the additional change in cross sectional area. This would require less centripetal energy to drive fluids through the device. It would also allow for easier fabrication of microfluidic networks on the disc since less area on the disc would be required when forming joints between reservoirs and inlet/outlet channels.

8. Also, the Examiner would like to note the correcting of the rejection involving the references Kellogg and Sheppard, Jr. In the previous action, the Examiner forgot to include the reference Burns when making the 103 rejection of claims 27, 28 and 41. This has now been corrected.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DKH
September 21, 2004

Jill Warden
Supervisory Patent Examiner
Technology Center 1700